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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,785	09/17/2007	Yingru Wu	76935/JPW/YC	7111

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,785	WU ET AL.	
	Examiner	Art Unit	
	STUART F. BAUM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *117-142* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *117,119,120,123,127,129,131,133,135-137 and 139* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/15/2007, 12/24/2009, 9/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence search result*.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 118,121,122,124-126,128,130,132,134,138 and 140-142.

DETAILED ACTION

1. Claims 117-142 are pending.

Claims 1-116 have been canceled.

Claims 117-142 have been newly added.

2. Applicant's election with traverse of Group I, i.e. claims drawn to a method of altering fibre initiation and/or elongation comprising manipulating a plant such that the production of a polypeptide is modified, wherein the polypeptide is a transcription factor, regulatory protein or a cell cycle protein, wherein the method comprises recombinantly expressing the polypeptide in said plant in the reply filed on 7/1/2010 is acknowledged. Applicants contend new claims 117-142 recite subject matter common to the invention of purported Group I. The traversal is on the ground(s) that Takatsuji et al. do not disclose a polypeptide exhibiting at least 95% identity to SEQ ID NO:38 and therefore the special technical feature linking new claims 117-142 has not been taught. Therefore, Applicants contend they are entitled to prosecution of all new claims (page 6 of Remarks, 1st full paragraph).

This is not found persuasive because Pursuant to 37 CFR 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited method, i.e., a method of altering fibre initiation and/or elongation in a fibre producing plant; a product used in the method, i.e., an isolated and/or exogenous polynucleotide; a product made by the method, i.e., a transgenic plant; and a process of using the product, i.e., a process for producing fibre comprising the transgenic plant. Further pursuant to 37 CFR

1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

The Office contends the special technical feature of Applicants' invention is a method of altering fibre initiation and/or elongation comprising genetically manipulating a plant such that the production of a polypeptide is increased, wherein the amino acid sequence of the polypeptide is at least 95% identical to the amino acid sequence of the polypeptide encoded by SEQ ID NO:38. The special technical feature is not shared or linked to a method of altering fibre initiation and/or elongation comprising decreasing expression or production of said polypeptide of Group II, and is not linked or shared by the method of assessing the potential of a fibre producing plant, which is not shared of linked to a isolated polypeptide of Group IV, which is not shared or linked to a polynucleotide which is a catalytic polynucleotide of Group VI, which is not shared or linked to a method of breeding a fibre producing plant of Group VII, or which is not shared or linked to a method of identifying an agent which alters fibre initiation and/or elongation of Group VIII.

The requirement is still deemed proper and is therefore made FINAL.

Claims 118, 121-122, 124-126, 128, 130, 132, 134, 138 and 140-142 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 117, 119-120, 123, 127, 129, 131, 133, 135-137 and 139, including SEQ ID NO:38 and 12, are examined in the present office action.

Information Disclosure Statement

4. The Information Disclosure Statement filed 11/15/2007 has not been considered because the citations listed on the IDS are duplicates of the citations listed on the IDS filed 12/24/2009.

Claim Objection

5. Claims 119 and 123 are objected to for being drawn to non-elected inventions. Correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 127, 129, 131, 133, 135, 137 and 139 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection included dependent claims.

The term "high stringency conditions" in claim 127 is a relative term which renders the claim indefinite. The term "high stringency conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 137 recites the limitation "The transgenic seed". There is insufficient antecedent basis for this limitation in the claim.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 117, 120, 123, 127, 129, 131, 133, 135, 137 and 139 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of altering fibre initiation and/or elongation in a fibre producing plant comprising genetically manipulating the plant such that the production of a polypeptide exhibiting at least 95% identity to the protein encoded by SEQ ID NO:38 is increased, or wherein the genetic manipulation comprises exposing the plant to a vector comprising a nucleotide sequence encoding said polypeptide, or wherein the plant is a species of the genus Gossypium, or an isolated and/or exogenous polynucleotide which hybridizes to any of the polynucleotide sequences listed in claim 127 (i-iii); vector, host cell, transgenic plant comprising said polynucleotide.

Because of the 112 2nd rejection of "high stringency conditions" as discussed above, the Office interprets "high stringency conditions" to mean any hybridization condition.

Applicants disclose SEQ ID NO:38 is the GhMyb25-like cDNA (clone ON038N8), entire clone coding region and that SEQ ID NO:12 is a partial protein encoded by GhMyb25-like cDNA (clone ON038N8) (pages 17-18).

The Applicants do not identify essential regions of the protein encoded by SEQ ID NO:38, nor do Applicants describe any polynucleotide sequences that hybridize to any of the sequences listed in claim 127(i-iii).

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a protein falling within the scope of the claimed genus of polynucleotides which hybridize to any of the sequences listed in claim 127(i-iii) and have the requisite activity to be operable in Applicants' invention. Applicants only describe a single cDNA sequence of SEQ ID NO:38.

Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the protein encoded by SEQ ID NO:38, it remains unclear what features identify an said protein. Both the prior art and the specification fail to disclose a correlation between the structure of the claimed sequences and the recited function. Since the genus of proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Enablement

8. Claims 117, 119-120, 123, 127, 129, 131, 133, 135-137 and 139 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior

art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method of altering fibre initiation and/or elongation in a fibre producing plant comprising genetically manipulating the plant such that the production of a polypeptide exhibiting at least 95% identity to the protein encoded by SEQ ID NO:38 is increased, or wherein the protein comprises the amino acid sequence of SEQ ID NO:12, or wherein the genetic manipulation comprises exposing the plant to a vector comprising a nucleotide sequence encoding said polypeptide, or wherein the plant is a species of the genus Gossypium, or an isolated and/or exogenous polynucleotide comprising SEQ ID NO:38, or comprising a nucleotide sequence which is at least 95% identical to SEQ ID NO:38, or which encodes a polypeptide which is at least 95% identical to the polypeptide encoded by SEQ ID NO:38 or which hybridizes to any of the polynucleotide sequences listed in claim 127 (i-iii); vector, host cell, transgenic plant comprising said polynucleotide or process for producing fibre comprising obtaining said transgenic plant so as to thereby produce the fibre.

Because of the 112 2nd rejection of "high stringency conditions" as discussed above, the Office interprets "high stringency conditions" to mean any hybridization condition.

Applicants disclose SEQ ID NO:38 is the GhMyb25-like cDNA (clone ON038N8), entire clone coding region and that SEQ ID NO:12 is a partial protein encoded by GhMyb25-like cDNA (clone ON038N8) (pages 17-18).

Applicants have not reduced to practice their invention. Applicants have not increased expression of any of the claimed sequences in a plant and produced a plant exhibiting an altered fibre initiation and/or elongation. Applicants have not transformed any plant with said sequence

or genetically manipulated the plant such that the production of said polypeptide is increased. Applicants have only indicated that the isolated polynucleotide encodes a GhMyb25-like polypeptide. The state-of-the-art teaches MYB transcription factors are involved in a wide array of plant biochemical processes and would produce unexpected results when transformed into a plant. Cedroni et al (2003, Plant Molecular Biology 51:313-325) teach six R2R3 MYB transcription factors were isolated from a cotton cDNA library using the highly conserved DNA-binding domain as a probe (page 314, left column, 1st full paragraph). Cedroni et al also disclose that R2R3-MYB family transcription factors are involved in a diverse range of biochemical pathways (page 314, left column, 2nd full paragraph) and therefore it is unclear if transforming a plant with Applicants' SEQ ID NO:38 or if increasing expression of SEQ ID NO:38 in a plant will alter fibre initiation and/or elongation.

The state-of-the-art teaches over-expressing the GhMyb25 nucleic acid cDNA produces unexpected results. Machado et al (2009, The Plant Journal 59(1):52-62) disclose that over-expression of the GhMyb25 cDNA in Gossypium produced plants that were infertile, ones that had increased number of leaf trichomes and developmental timing of fibre initiation was not altered. Machado et al disclose that fibre initial number was increased compared to control plants (page 56, right column).

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that are 95% sequence identical to SEQ ID NO:38 will encode a protein with the same activity as a protein encoded by SEQ ID NO:38. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid

substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

Applicants have not provided any teachings for one skilled in the art to predict and isolate nucleic acid sequences that encode a protein with the necessary activity to be operable in Applicants' invention. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences. Therefore, the instant specification fails to provide guidance for which amino acids of the protein encoded by SEQ ID NO:38 can be altered, the type of alteration, and which amino acids must not be changed, to maintain activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:38 as probes or by designing primers to undisclosed regions of SEQ ID NO:12 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify

those, if any, that when over-expressed modify fibre initiation and/or elongation or undue trial and error experimentation would be required to screen plants that have been genetically manipulated in any way for those, if any, that exhibit an increase expression of said polypeptide and exhibit an altered fibre initiation and/or elongation.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 131 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claim recites "A host cell comprising" which reads on a human being. Amending the claim to recite "An isolated host cell" will obviate the rejection.

10. Claim 137 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 137 is drawn to a seed of a transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other

distinguishable characteristics of the claimed progeny (seeds), it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy , Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the seeds comprise the polynucleotide that was introduced into the parent would overcome the rejection.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 127, 129, 131, 133, 137 and 139 are rejected under 35 U.S.C. 102(e) as being anticipated by Fincher (1999, Pub. No.: US 2004/0123338 A1).

The claims are drawn to an isolated polynucleotide that hybridizes to any of the sequences listed in claim 127(i-iii) under high stringency conditions; vector, host cell, transgenic plant, transgenic seed and process for producing fibre comprising obtaining the transgenic plant so as to thereby produce fibre.

Fincher discloses a nucleic acid molecule of SEQ ID NO:3964 which exhibits 23% identity to Applicants' SEQ ID NO:38 (sequence search results included) which the office contends would hybridize with applicants' SEQ ID NO:38 and Fincher discloses a plant transformed therewith (see claims 1-9). Fincher teaches vectors and host cells comprising said nucleic acid molecule, and a process for producing fibre comprising obtaining the transgenic plant so as to produce fibre, and as such, Fincher anticipates Applicants' claimed invention.

12. The claims are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:38 encoding SEQ ID NO:12 and plant transformation therewith.

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
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Primary Examiner
Art Unit 1638
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